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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,437	09/16/2003	Paola Minoprio	03495-0200-02	2639

22852 7590 07/28/2005

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,437	MINOPRIO ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *79-109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 79-80, 83, 86 and 90 are drawn to a nucleic acid molecule and kit classified in class 536, subclass 23.1. Further species election required.

Group II. Claims 81 and 95-96 are drawn to a polypeptide, composition and vaccine, classified in class 530, subclass 350. Further species election required.

Group III. Claims 82 and 91 are drawn to antibodies and kit in classified in class 530, subclass 387.1.

Group IV. Claims 84-85 are drawn to a method for the production of a Tc45 polypeptide classified in class 435, subclass 68.1.

Group V. Claim 87 is drawn to an immunological complex classified in class 424, subclass 69.3.

Group VI. Claims 88 are drawn to a method of detecting a parasite classified in class 435, subclass 6.

Group VII. Claims 89 are drawn to a method of detecting a parasite classified in class 435, subclass 7.22.

Group VIII. Claim 92 is drawn to a method of screening for active molecules classified in class 435 subclass 4.

Group IX. Claim 93 is drawn to a method of preparing an eukaryotic protein classified in class 435, subclass 68.1.

Group X. Claim 94 is drawn to a method for detecting a *T. cruzi* infection classified in class 435, subclass 7.22.

Group XI. Claim 97 is drawn to a method for screening a molecule classified in class 435, subclass 4.

Group XII. Claims 98-99 are drawn to a method of inhibiting an eukaryotic protein classified in class 435, subclass 7.6.

Group XIII. Claims 100-102 are drawn to a method for producing an eukaryotic recombinant amino acid racemase classified in class 435, subclass 69.1.

Group XIV. Claim 103 is drawn to a method for producing D-amino acid classified in class 530, subclass 300.

Group XV. Claims 104-107 are drawn to a method of preventing or inhibiting infection by virus or protozoan classified in class 435, subclass 7.22.

Group XVI. Claim 108 is drawn to a method of detecting a eukaryotic protein classified in class 435, subclass 7.4.

Group XVII. Claim 109 is drawn to a molecule for preventing or treating a parasite or virus infection classified in class 424, subclass 191.1.

2. Groups I, II, III, V and XVII are related as different products. The products of Groups I, II, II, V and XVII differ structurally and functionally.

3. Groups I and IV are unrelated as product and method of making that product. The product of Group I is not needed for the method of Group IV. The products are independent and distinct as claimed.

4. Groups I and (VI and XIII) are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h). In the instant case, the product of Group I can be used as molecular probes.

5. Groups I and (VII, IX, X, XI, XII, XIV, XV and XVI) are unrelated as product and process of use. The product of Group I is not required for the methods of Groups VII, IX, X, XI, XII, XIV, XV and XVI. The Groups are independent and distinct as claimed.

6. Groups II and (IV, IX and XIII) are related as process of making and product made. The Groups are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, polypeptide of Group II can be made synthetically.

7. Groups II and (VII, VIII, X, XI, XII, and XV) are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h). In the instant case, the polypeptide of Group II can be used in antibody detection.

8. Groups II and (XIV and XVI) are unrelated as product and process of use. The product of Group II is not needed for the methods of Groups XIV and XVI. The products are independent and distinct as claimed.

9. Groups III and (IX and XIII) are unrelated as process of making and product made. The product of Group III is not required for the methods of Groups IV. The Groups are independent and distinct as claimed.

10. Groups III and VII are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h). In the instant case, the antibodies of Group III can be used for passive immunization studies.

11. Groups III and (VI, IV, VIII, X, XI, XII, XIV, XV, and XVI) are unrelated as product and process of use. The product of Group III is not required for the methods of Groups VI, IV, VIII, X, XI, XII, XIV, XV and XVI . The Groups are independent and distinct as claimed.

12. Groups IV, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV and XVI are related as different methods. The methods differ because they have different goals, require different method steps and parameters.

13. Groups IV and V are unrelated as process of making and product made. The product of Group V is not required for the methods of Groups IV. The Groups are independent and distinct as claimed.

14. Groups V and (IX, XIII, XIV) are unrelated as process of making and product made. The product of Group V is not required for the methods of Groups IX, XIII and XIV. The Groups are independent and distinct as claimed.

15. Groups V and (VI, VIII, X, XI, XV and XVI) are unrelated as product and process of use. The product of Group V is not required for the methods of Groups VI, VIII, X, XI, XV and XVI. The Groups are independent and distinct as claimed.

16. Groups V and Group VII are drawn to a product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h). In the instant case, the product of Group V can be used in affinity chromatography studies.

17. Groups (VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI) and XVII are unrelated as product and process of use. The product of Group XVII is not needed for the methods of Groups VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV and XVI . The products are independent and distinct as claimed.

18. Groups XVII and (IX, XIII and XIV) are unrelated as process of making and product made. The product of Group XVII is not needed for the methods of Groups IX, XIII and XIV). The products are independent and distinct as claimed.

19. Groups XVI and XII are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MEP 806.05(h). In the instant case, the product of Group XVII can be used as components in vaccine compositions.

SPECIES ELECTION

20. Group I, IV, VI and VIII, contains claims that recite a plurality of disclosed patentably distinct inventions with distinct species. Applicant is advised to elect a species and then elect one sequence or species within the elected species. For Example, elect Species A and further elect: SEQ ID NO: 8.

Species A, Select one nucleic acid molecule selected from the group consisting of SEQ ID Nos:8-11.

Species B, Select one nucleic acid molecule that encodes a peptide selected from the groups consisting of SEQ ID Nos. 1-4.

Species C, Select one nucleic acid molecule that hybridizes to a nucleic acid molecule of species of Species A or Species B.

Species D, a nucleic acid molecule that is derived by *in vitro* mutagenesis from SEQ ID Nos. 8-11.

Species E, a nucleic acid molecule that is degenerated from SEQ ID Nos. 8-11 as a result of the genetic code.

Species F, a nucleic acid molecule that encodes Tc45 polypeptides, variants or homologs thereof.

Species G, a nucleic acid molecule that encodes an eukaryotic protein with an amino acid racemase activity.

Species H, a nucleic acid that encodes an eukaryotic protein with proline racemase activity.

Species I, a nucleic acid molecule that encodes an eukaryotic protein which is recognized by antibodies raised against an eukaryotic protein having proline racemase activity.

Species J, a nucleic acid molecule that has at least 80% of the identity with the sequence of an eukaryotic gene encoding a protein with racemase activity and a molecule that is a fragment of a polynucleotide containing at least 50 nucleotides of the sequence of the proline racemase gene of *T. cruzi* or hybridizing under stringent conditions with a polynucleotide according to any one of SPECIES G, H, I or J.

Species K, a nucleic acid molecule that is a fragment of a polynucleotide containing at least 50 nucleotides of the sequence of the proline racemase gene of *T. cruzi* or hybridizing under stringent conditions with a polynucleotide according to any one of SPECIES G, H, I or J.

21. Group II, III, V, VII, IX, X, XI, XII, XIII, XIV, XV, XVI and XVII contains claims that recite a plurality of disclosed patentably distinct inventions with distinct species. Applicant is advised to elect for the species, a species and then elect one sequence or species within the elected species. For example, elect Species A (a polypeptide encoded by a nucleic acid molecule of claim 79) and then further elect: (a) a purified nucleic acid molecule selected from SEQ ID NO: 11.

Species A, polypeptide that is encoded by a nucleic acid molecule of Group I (claims 79-80, 83, 86 and 90).

Species B, a polypeptide that has a molecular weight of approximately 45kDa as determined by SDS-PAGE which is post translationally modified or not.

Species C, a polypeptide that is an eukaryotic protein with proline racemase activity.

Species D, a polypeptide which is an eukaryotic protein with proline racemase activity, which is a P38 to P45 kDa protein.

Species E, a polypeptide that is P38 to P45 kDa protein according to Species D, which is a parasite protein.

Species F, a polypeptide that is P38 to P45 kDa protein according to Species E, wherein the parasite is *T cruzi.*

Species G, a polypeptide that is a purified eukaryotic amino acid racemase having a molecular weight of 38 kDa to more or less 10%.

Species H, a polypeptide that is a Tc45 polypeptide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

22. The inventions are distinct, each from the other because of the following reasons: Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

23. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

24. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

25. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

26. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
July 11, 2005

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